

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,073	12/12/2000	Shirin Asina	ROGO-214.2-Cont	3402

24972 7590 09/23/2003  
FULBRIGHT & JAWORSKI, LLP  
666 FIFTH AVE  
NEW YORK, NY 10103-3198

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 09/23/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/735073

Applicant(s)

Asina et al

Examiner

Hoff

Group Art Unit

6651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☒ Responsive to communication(s) filed on 6/30/03
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 115-122 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 115-122 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1651

The amendment of 6/30/03 canceled claims 1-114.

Claims examined on the merits are 115-122, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5

***Claim Rejections - 35 USC § 112***

Claims 121 and 122 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10

The specification fails to describe a composition as required by the claims as being an invention.

***Response to Arguments***

Applicants point to Examples 9 and 10 in patent 5,888,497 that issued from parent 08/745,063. However, the examples do not support an invention of the breadth and scope of claims 121 and 122. The procedures of the examples involve much more than a composition containing only a medium and a material that suppresses cancer cell proliferation, and the composition being frozen.

15

***Claim Rejections - 35 USC § 112***

Claims 115, 117 and 119-122 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the material that suppresses proliferation of cancer cells having a molecular weight of at least about 30 kd as disclosed in the specification at page 21, lines 17-20 when producing a conditioned culture medium as required by claims 115 and 117, does not reasonably provide enablement for producing a material having a molecular weight below 30 kd that suppresses proliferation of cancer cells as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

20

The specification describes the material that suppresses proliferation of cancer cells as having a molecular weight of at least 30 kd, and does not indicate that material less than 30 kd can provide the function of suppressing proliferation of cancer cells.

***Response to Arguments***

5 Applicants refer to the parent '063 application as not referring to 30kd. However, this application does not disclose a method and composition as presently claimed.

***Claim Rejections - 35 USC § 103***

Claims 115-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (WO 97/36495).

10 The claims are drawn to producing a conditioned culture medium which has a cancer cell proliferation-inhibiting effect by a process of entrapping cancer cells in a proliferation-restrictive selectively permeable structure, culturing the entrapped cancer cells in a culture medium where growth of the cells is restricted by the cells being entrapped so that the cells produce a material that suppresses proliferation of cancer cells which permeates the structure into the culture medium to produce the  
15 conditioned culture medium, and the conditioned medium is recovered. In claim 117, the recovered conditioned medium is frozen.

Jain et al disclose encapsulating cancer cells in capsules such that proliferation of the cells is restricted during growth and the restricted cancer cells produce more of a cancer suppressing substance than when not restricted. The encapsulated cells can be implanted in a subject to produce the substance  
20 and suppress cancer in the subject. Jain et al further disclose (page 16, lines 14-16) that the encapsulated cells can be cultured *in vitro* to produce diffusible products that move into the culture medium where the products can be collected.

In view of the *in vitro* culturing of entrapped cancer cells in a culture medium as disclosed by Jain et al, it would have been obvious to recover the culture medium after culturing since the culture medium

would have been expected to contain the cancer cell suppressing material. Freezing the medium after recovery would have been obvious to preserve the medium.

Jain et al is a reference since parent application 08/745,063 is not enabling for the claimed invention, and Jain et al was published more than one year before filing the instant application.

5

***Response to Arguments***

Applicants urge that the '063 application antedates Jain et al. However, present invention is not described in the '063 application, and Jain et al was published more than one year before filing of the instant application. There is no disclosure in the '063 application of recovering the culture medium as a conditioned culture medium.

10

Applicants refer to Patent 6,224,912 as being allowed. However, the invention claimed in the patent is not described in the '063 application, and the patent claims an invention different than presently claimed that is unobvious over Jain et al. As to claims 116 and 118 that require a material having a molecular weight of at least about 30 kd, this material is inherently in the diffusible products disclosed by Jain et al. Claims 116 and 118 do not require the method of the claims of Patent 6,224,912, and the

15

present claims are rejectable even through the patent claims are allowable.

***Double Patenting***

20

Claims 115-122 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,224,912 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention of producing a conditioned culture medium would have been obvious from the claims of the patent requiring culturing entrapped restricted cancer cells in a culture medium to produce a material that suppresses cancer cell proliferation.

***Response to Arguments***

In response to the above double patent rejection, applicants assert they reserve the right to file a terminal disclaimer to overcome the rejection over the 6,224,912 Patent, but submit that at least claims without the 30 kd subject matter should not be subject to the rejection. However, the material of the present claims is not excluded from having a molecular weight of 30 kd, and the claims encompass the at least 30kd material in the claims of the patent.

***Double Patenting***

Claims 115-122 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,888,497 in view of Jain et al (WO 97/36495).

It would have been obvious to culture in a medium *in vitro* the entrapped cancer cells that produce a cancer suppressing material of the patent claims to allow the cancer suppressing material to diffuse into the medium and recover the medium as suggested by Jain et al (WO 97/36495) disclosing (page 16, lines 14-16) culturing restricted encapsulated cells *in vitro* in a culture medium to produce diffusible products that move into the culture medium where the products can be collected.

***Response to Arguments***

No response was made to this double patenting rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Application/Control Number: 09/735,073

Page 6

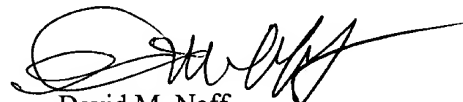
Art Unit: 1651

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be  
5 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the  
10 receptionist whose telephone number is 703-308-0196.



David M. Naff  
Primary Examiner  
Art Unit 1651

15 DMN  
9/22/03